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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,111	CAWTHON, RICHARD	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/19/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present Office Action is responsive to the Amendment received on February 25, 2008.

Preliminary Remark

Claims 1-13 are pending and are under prosecution.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 19, 2007 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

With regard to Applicants' statement regarding the provisional application, 60/442,456[1], it is submitted that Applicants are claiming priority to said application under 119(e).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is self-dependent.

For the purpose of prosecution, it is assumed that claim 7 is dependent on claim 6, as claim 6 provides the only antecedent basis for the limitations found on claim 7.

Claim 13 recites "The" method.

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[1] Found on page 2 of the IDS statement letter.

Claim 13 is an independent claim, so it would appear that the claim should be recited as being "A" method.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-10 and 13 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, made in the Office Action mailed on August 23, 2007 is maintained for the reasons already of record.

Claims 11 and 12 are included herein as being new grounds.

The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' arguments presented in the Amendment received on February 25, 2008 have been fully considered but they are not found persuasive for the reasons set forth in the, "Response to Arguments" section.

The Rejection:

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in In Re Wands (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

The present enablement rejection is based on the large breadth of the claims which cover a method of predicting a death of human being based on the length of a telomere, the death of which is not associated with any kind of conditions, such as infectious diseases or physical ailing conditions.

Nature of the Invention, Breadth of Claims & Unpredictability of the Art:

Presently, there is no method that is available in the art that is capable of predicting how long a person may live. While the present invention appears to be directed to predicting the survival of an organism, in particular, human, wherein said organism is suffering from some kind of ailment, with explicit embodiments drawn to infectious diseases or cardiovascular diseases, the presently claimed breadth covers art which is completely unpredictable, that is, a method of predicting how long a person may live. To this breadth, the instant invention is simply not enabling.

Absence of working examples and Absence of Guidance:

The instant specification provides neither guidance nor working examples to this embodiment.

State of Prior art:

There is no prior art currently that is capable of detecting how long a person may live in general.

Skill level of the Artisan and Conclusion:

As discussed above, the invention as claimed cannot be enabling for a skilled artisan to predict the longevity of a person who is not ailing from any kind of physical ailing conditions, strictly by determining the length of telomere or the rate of disease in telomere without undue experimentation, as the prior art provides no evidence that such can be done, and the specification alike.

Response to Arguments:

Applicant traverses the rejection.

Applicant states that although Applicant does not believe the claims as originally presented are accurately characterized by the examiner, Applicant has amended the claims to all for a method of determining the mortality risk of an organism rather than survival of an organism (page 4, 4th paragraph, Response).

Currently, the claims are drawn to a method which determines the risk of mortality (i.e,. death) in an organism simply by correlating the length of an organism's telomere length with telomere lengths which are associated with mortality risk, derived from a population of organism.

Applicants state that Figures 4 and 5 provide a "dramatic" demonstration of the subject matter claimed. (page 4, 5th paragraph, Response)

It is unclear from what aspect of these Figures, Applicant's representative is deriving the term, "dramatic," but it is respectfully submitted that the Figures, at best, demonstrate the unreliability of the disclosed method.

According to Figure 4, blood samples were drawn from a population of people to determine the length of their telomeres, and a percentage of people who has survived varying numbers of years is plotted.

Figure 4 shows that evidences that **a significant population** of people with "shorter" telomere length lives ***as long as*** those with "longer" telomere lengths. Around 15th year after the blood draw, about 20% lesser number of people who were designated as having shorter telomere length were living when compared to those who were designated as having longer telomere length (see page 6, section [0022] of the specification).

The first figure of Figure 5 shows a survival trend of those whose blood was drawn around 60-74 years of age, which is similar to that which was found on Figure 4.

The second figure of Figure 5 shows even a lesser difference in the likelihood of survival between those who were designated as having longer and shorter telomere lengths (less than a percent).

This is to say that a significant number of people who were designated as having so called, "longer" telomere length lived as long as those having "shorter" telomere length.

In addition, the specification disclose that out of 143 research subjects ranging from ages 60-97 years, 101 people died by mid-2002 and for the remaining 42 subjects, the date at which they were ***last known to be alive was established.*** (see page 30, section [0094]). In other words, even from a small pool or research subjects, the survival trend of about ***30%*** of the research subjects were ***estimated***.

What Applicants are attempting to derive therefore, is statistical relevance from known survival trend of ***101*** research subjects, the age of people which range from 60-97 years. In addition, out of these 101 research subjects whose survival trend was definitely known, the specification does not even disclose how many of these subjects were deemed to have "shorter" telomere versus those who had "longer" telomeres. Provided that equal number of people had longer and shorter telomere lengths (50 people each), the actual difference in the number of people with longer telomere length out living those with shorter telomere length amounts to **a single person**.

It is respectfully submitted that such is not a "dramatic" demonstration as Applicant's representative asserts.

In addition, the claims require that based on the telomere length of the subject, one should be able to determine the mortality risk, by comparing it with telomere length derived from a

population. This would require that one have some statistical trend be established based on varying telomere lengths and a number of years of survival based on those varying telomere lengths.

However, Applicants based on their discovery on classifying the subjects as having either: a) a longer telomere; and b) a shorter telomere, wherein the cut-off point between the two classification was based on who were on "top half of the TL [telomere length] distribution." (page 6, section [0022]).

There is no correlation, teaching or guidance whatsoever as to how one of skill in the art can determine the mortality risk of a subject of particular telomere length.

With regard to claims 11 and 12, the specification is even less enabling in that it does not demonstrate how one can determine that a subject is at an increased risk for mortality from a particular type of disease, such as infectious/cardiovascular disease, **strictly based on telomere lengths**. To this, the specification is completely silent in demonstrating/guiding a skilled artisan.

For the above reasons, it is respectfully submitted that one of skill in the art would not be able to practice the invention without undue experimentation.

The rejection is maintained therefore.

Claim Rejections - 35 USC § 103

The rejection of claims 1-3, 8-10, and 13 under 35 U.S.C. 103(a) as being unpatentable over Bechter et al. (Cancer Research, November 1998, vol. 58, pages 4918-4922), made in the Office Action mailed on August 23, 2007, is withdrawn in view of a careful reconsideration.

The rejection of claims 1-3, 8-10, and 12 under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (PNAS, USA, 1995, vol. 92, pages 11190-11194) made in the Office Action mailed on August 23, 2007, is withdrawn in view of a careful reconsideration.

The rejection of claims 1-3 and 6-11 under 35 U.S.C. 103(a) as being unpatentable over Palmer et al. (The Journal of Experimental Medicine, 1997, vol. 185, no. 7, pages 1381-1386), made in the Office Action mailed on August 23, 2007, is withdrawn in view of a careful reconsideration.

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Bechter et al. (Cancer Research, November 1998, vol. 58, pages 4918-4922) as applied to claims 1-3 and 8-10 above, and further in view of Kim et al. (Science, 1994, vol. 266, pages 2011-2015) made in the Office Action mailed on August 23, 2007, is withdrawn in view of a careful reconsideration.

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (PNAS, USA, 1995, vol. 92, pages 11190-11194) as applied to claims 1-3, 8-10, and 12 above, and further in view of Kim et al. (Science, 1994, vol. 266, pages 2011-2015) made in the Office Action mailed on August 23, 2007, is withdrawn in view of a careful reconsideration.

The rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Palmer et al. (The Journal of Experimental Medicine, 1997, vol. 185, no. 7, pages 1381-1386) as applied to claims 1-3 and 6-11 above, and further in view of Kim et al. (Science, 1994, vol. 266, pages 2011-2015) made in the Office Action mailed on August 23, 2007, is withdrawn in view of a careful reconsideration.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot

guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner
Art Unit 1637
5/12/2008